FINAL REPORT
OF THE
INTERIM STUDY COMMITTEE ON
HEALTH ISSUES

Indiana Legislative Services Agency
200 W. Washington Street, Suite 301
Indianapolis, Indiana 46204

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INDIANA LEGISLATIVE COUNCIL

1998

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INTERIM STUDY COMMITTEE ON HEALTH ISSUES

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I. LEGISLATIVE COUNCIL DIRECTIVE

The Interim Study Committee on Health Issues was created by Legislative Council Resolution 98-2 to study the following issues:

Issue 1 Study effects on consumers of changes in prescriptions of narrow therapeutic index drugs from one manufacturer to another. (HCR 22)
Issue 2 Study the use by health care providers of powdered latex gloves. (HB 1085)
Issue 3 Analyze issues relating to hospices. (SR 15)
Issue 4 Study certification and compliance standards for narcotic treatment programs. (SCR 49)
Issue 5 Study changes that have been made in the state employee health insurance program during the past 10 years, including changes in costs to participants, covered services, claims payments and other program administrative matters. Gather comparative information concerning the state employee health program in other states.
Issue 6 Study issues related to mandatory testing of newborn infants or pregnant women for HIV. (SCR 65)

II. INTRODUCTION AND REASONS FOR STUDY

Issue 1 Narrow Therapeutic Index Drugs

House Concurrent Resolution 22 urged the Legislative Council to establish a study committee to study effects on consumers of changes in prescriptions of narrow therapeutic index (NTI) drugs from one manufacturer to another. NTI drugs are drugs for which drug blood levels within a narrow range are therapeutic. Amounts of the NTI drug in the blood outside of that range could put the patient at risk. Current Indiana law does not specifically address NTI drugs. Proponents of legislation believe that physician notification when drug interchanges are made is imperative to insure optimum management of patients taking those particular drug products because drugs with the NTI label require very careful monitoring due to the narrow range between patient benefit and risk. Opponents of legislation believe that there is no scientific evidence supporting this assumption and that generic drugs must be approved by the federal Food and Drug Administration which has adequate standards in place, so legislation is not necessary.

Issue 2 Powdered Latex Gloves

House Bill 1085 urged the Legislative Council to establish an interim study committee to study the use by health care providers of powdered latex gloves. The introduced version of HB 1085 would have regulated the use of powdered latex gloves. Current Indiana law does not address the issue. Proponents of legislation are concerned with the problems caused by sensitization resulting from regular exposure. Opponents of legislation believe that the issue is best addressed by federal agency guidelines and regulation, and by education and research.

Issue 3 Hospice Licensure

Senate Resolution 15 urged the Legislative Council to form a study committee to analyze issues relating to hospices. Current Indiana law provides for voluntary certification of hospices, but does not require licensure or grievance procedures.

Interest in mandatory hospice licensure in 1998 resulted in SR 15.

Issue 4 Narcotic Treatment Programs

Senate Concurrent Resolution 49 urged the Legislative Council to establish a study committee to study certification and compliance requirements for narcotic treatment programs. Current Indiana law provides for certification of narcotic treatment facilities by the Division of Mental Health. Proponents of legislation are interested in statutorily requiring specific criteria and requirements for use by the Division in certifying new narcotic treatment facilities.

Issue 5 State Employee Health Benefits

The study of changes that have been made in the state employee health insurance program during the past 10 years was suggested by General Assembly leadership. The study was to include: (1) changes in costs to participants, covered services, claims payments and other program administrative matters; and (2) gathering of comparative information concerning the state employee health program in other states. Current Indiana law allows for the Indiana State Personnel Department to establish self-insurance programs and to contract for prepaid health care delivery for state employees.

Issue 6 HIV Testing

Senate Concurrent Resolution 65 urged the Legislative Council to establish an interim study committee to examine whether to mandate testing of newborn infants or pregnant women for HIV and the antibodies or antigen to HIV, and to examine all financial aspects related to the testing and treatment of persons who test positive.

III. SUMMARY OF WORK PROGRAM

Issue 1 Narrow Therapeutic Index Drugs and Generic Drug Law

The Committee met on June 24, 1998 at the State House. The Committee heard testimony from several individuals representing drug companies, pharmacists, physicians and consumers. Committee members asked questions of those testifying throughout the testimony. A draft was prepared following the meeting for presentation to the Committee on September 2, 1998. An additional draft amending the current Indiana generic drug law was also drafted for presentation to the Committee on September 2, 1998 due to interest generated by the testimony concerning narrow therapeutic index drugs.

Issue 2 Powdered Latex Gloves

The Committee met on July 29, 1998 at the State House. The Committee heard testimony and asked questions of several individuals representing glove manufacturers, health care providers and individuals with latex allergy. The Committee requested that a concurrent resolution be drafted for review. The Committee heard testimony on the concurrent resolution on September 2, 1998.

Issue 3 Hospice Licensure

The Committee met on August 12, 1998 at the State House. The Committee heard testimony from individuals representing the hospice industry and hospice patients, as well as state agency personnel. The Committee determined that a hospice licensure bill should be drafted for review by the Committee. PD 3201 was drafted, but due to lack of

consensus regarding content, was not reviewed by the Committee. The Committee determined that interested parties should continue to work together to come to consensus on a bill which could be introduced during the 1999 session of the General Assembly.

Issue 4 Narcotic Treatment Programs

The Committee met on July 8, 1998 at the State House. The Committee heard testimony from individuals representing neighborhoods, narcotic treatment facilities, law enforcement, and from state agency personnel. PD 3172 was drafted for Committee review.

Issue 5 State Employee Health Benefits

The Committee met on July 8, 1998 at the State House. The Committee heard testimony from various individuals regarding state employee health benefits, including state agency personnel. PD 3195 was drafted for the Committee, but was not heard due to perceived problems.

Issue 6 HIV Testing

No action was taken on this issue.

IV. SUMMARY OF TESTIMONY

The Committee heard the following testimony from interested parties representing a variety of viewpoints on the issues considered by the Committee:

Issue 1 Narrow Therapeutic Index Drugs

Proponents of legislation regulating NTI drugs stated that (1) physician involvement is important when generic to brand, brand to generic, or generic to generic interchange is made to insure optimum management of patients, and (2) scientific discoveries cause physicians to change patient care strategies on an ongoing basis.

Other interested parties offered the following testimony: Indiana's generic substitution law was explained and it was noted that previous versions of the generic drug law required a pharmacist to receive a patient's consent before providing the patient with the generic form of a prescribed drug; however, that requirement is no longer in the statute. Anticompetitive, anticonsumer effects of regulating NTI drugs without compelling scientific evidence that regulation is necessary for optimum patient care were discussed. There was explanation that the FDA has systems in place to address a problem in this area if one arises. All generic drugs must meet FDA standards for FDA approval. Two categories of generic drugs exist--those with an "A" rating may be substituted with full confidence, while those with a "B" rating should not be substituted. This information may be found in the FDA's "Orange Book". The pharmacist and the prescribing physician know whether a generic drug is rated AB or BB. Substitution of one drug for another may only be made if the products are generically equivalent. Indiana uses no particular rating system for generic drugs, but does follow FDA standards.

Issue 2 Powdered Latex Gloves

About 1% to 6% of the general population and about 8% to 12% of regularly exposed health care workers are sensitized to latex according to scientific literature reported in

the NIOSH ALERT (DHHS (NIOSH) Publication No. 97-135). The powder in latex gloves can cause latex proteins to be released in the air and breathed in by others in the vicinity. The allergy is classified into three types, from mild skin irritation to severe reaction. There have been reported cases of individuals who have died from latex allergy. There are about 265 different proteins in latex, but it is not known which proteins are responsible for the allergy. Banning the use of powder in latex gloves may or may not reduce the incidence of latex allergy. More scientific research in this area is needed. Various federal agencies are studying latex allergy and other types of gloves' effectiveness as barrier protection. There are arguments that latex gloves provide for: (1) better tactile sensation; and (2) barrier protection to bloodborne pathogens such as HIV and hepatitis. Existing OSHA regulations require latex gloves for barrier protection. A new national standard concerning latex gloves will probably be issued by the Food and Drug Administration and the National Institute for Occupational Safety and Health within the next year. OSHA is expected to issue new recommendations, which will have the force of law, by the end of the year. If Indiana implements policies, the policies may conflict with the new OSHA recommendations. The FDA is scheduled to issue latex labeling requirements this September. Hospitals and health professionals know about latex allergy, but not all use reduced protein or non-latex gloves. Factors to consider before taking action requiring alternative gloves are whether: (1) alternatives are readily available; (2) there will be any added cost; and (3) the alternatives are as good as latex gloves.

Issue 3 Hospice Licensure

Currently, certification of hospices is voluntary, and there are no criteria which must be met for an organization to call itself a "hospice". Indiana provides a Medicaid hospice benefit, but does not license hospices. Hospices in Indiana are surveyed approximately every 7 years. There is one hospital in Indiana currently offering in-patient hospice services. There are approximately 30-40 hospitals offering home health hospice services. There is concern that hospitals, home health agencies and nursing homes that provide hospice services would be required to be dually licensed with a hospice licensure law. Nursing homes sometimes contract with hospice providers to provide hospice services to the nursing home's patients. A licensed nursing home, which is not providing the hospice services, should not need additional licensure under a hospice licensure law. The hospice that is providing the services would need to be licensed. If, however, the nursing home wished to provide hospice services itself, it would need to be licensed under a hospice licensure law. Hospices also contract with nursing homes and hospitals to provide care to hospice patients requiring hospitalization for short term acute care and respite care in nursing homes. State certification of hospices mirrors federal certification. Federal certification is necessary for hospices which seek Medicare reimbursement.

Issue 4 Narcotic Treatment Programs

Proponents of legislation say that the objective is prevention of problems other states have encountered by having too little state supervision of methadone clinics. The statement was made that in 1997 the Division of Mental Health made a decision to stop surveying narcotic treatment facilities. Concerns about location of methadone clinics are more about occurrences outside the clinic than occurrences inside. Some of these concerns are: use of narcotics in addition to methadone; illegal drugs and sales; and crime drawn from outside the clinic area. The Marion County Board of Zoning Appeals has determined that methadone clinics and health care clinics are not the same and that

different zoning requirements should apply to each. Addiction clinics (methadone clinics and other narcotic treatment clinics) must be, and are, certified by the Division. Federal rules and regulations provide the clinic inspection authority which can be ceded to the states or shared with the states.

Issue 5 State Employee Health Benefits

Many concerns and thoughts about past and current state employee health benefits were expressed. There was particular attention to laboratory coverage and coverage for rural employees. The history of state employee welfare insurance coverage from 1978 to present was reviewed. HMO plans limit provider availability and traditional plans provide a certain payment for in network services and a lesser payment for out of network services (usually 20% less). Discussion centered on adequacy of in network service providers, especially for rural employees. Indiana State Personnel Department has convened a health care redesign committee to work toward improvements with the next contract.

Issue 6 HIV Testing

No testimony was received on this issue.

V. COMMITTEE FINDINGS AND RECOMMENDATIONS

Issue 1 Narrow Therapeutic Index Drugs and Generic Drug Law

The Committee made the following findings of fact concerning the issue of narrow therapeutic index drugs: No legislation on this issue is necessary at this time.

The Committee made no recommendations concerning the issue of narrow therapeutic index drugs.

The Committee made the following additional findings of fact concerning the current Indiana generic drug law: (1) The current generic drug law no longer requires that the customer be informed when a generic substitution is made. (2) The current generic drug law should be amended to clarify that only substitutions of generically equivalent drugs are allowed under the statute.

The Committee made the following recommendations concerning the current Indiana generic drug law: Support PD 3200, amending the current generic drug law, during the 1999 session of the General Assembly.

Issue 2 Powdered Latex Gloves

The Committee made the following findings of fact: (1) Latex allergy is an issue with a range of levels of severity for members of the health care professions and the general population. (2) The Committee should support further research and education on latex allergy and the use of powdered latex gloves.

The Committee made the following recommendations: Adopt a concurrent resolution encouraging further research and education regarding latex allergy and the use of powdered latex gloves. The concurrent resolution was adopted by the Committee on

September 2, 1998.

Issue 3 Hospice Licensure

The Committee made the following findings of fact: Hospice licensure is an issue which could be supported by the Committee. Consensus regarding the best form of legislation requiring hospice licensure has not yet been reached.

The Committee made the following recommendations: The issue should remain alive so that interested parties may continue to work on draft legislation until consensus is reached. Introduced legislation should include a provision requiring the Department of Health to report to the Health Finance Commission, prior to January 1, 2002, providing sufficient information to determine whether the federally-required and current surveying frequency of 10% of hospices per year is sufficient, or whether increased frequency should be required by statute.

Issue 4 Narcotic Treatment Programs

The Committee made the following findings of fact: There is currently a certification process for new narcotic treatment facilities.

The Committee made no recommendations concerning this issue.

Issue 5 State Employee Health Benefits

The Committee made the following findings of fact: There are problems with the current state employee health benefits, particularly with regard to laboratory services and coverage for rural employees.

The Committee made no recommendations concerning this issue.

Issue 6 HIV Testing

The Committee made no findings of fact or recommendations concerning this issue.

A copy of this report is available on the Internet. Reports, minutes, and notices are organized by committee. This report and other documents for this Committee can be accessed from the General Assembly Homepage at http://www.state.in.us.legislative/.

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